

## REMARKS

### Status of the Claims

#### *Pending claims*

Claims 21 and 26 to 53 are pending and under consideration. Claim 51 has been withdrawn from consideration.

#### *Allowed claims*

Applicants thank the Examiner for finding that claims 21 and 44 to 46 are allowable.

#### *Restriction Requirement*

In response to the Restriction Requirement mailed February 12, 2001, Applicants elected a sequence as set forth in SEQ ID NO:23, with traverse.

In the final office action of July 29, 2003, claim 51 (submitted in Applicants' response of May 09, 2003) was withdrawn from consideration for allegedly being directed to a non-elected invention.

#### *Claims amended and canceled in the instant amendment*

Claims 30, 36, 37 and 43 are canceled. Thus, after entry of the instant amendment, claims 21, 26 to 29, 31 to 35, 38 to 42, and 44 to 53 will be pending and under consideration.

Applicants respectfully request entry of the amendments set forth in this response under 37 CFR §1.116. The amendment places the case in condition for allowance and places the case in better condition for appeal; the amendment does not raise any issues of new matter; and, the amended and new claims do not present new issues requiring further consideration or search.

#### *Outstanding Rejections*

Claims 32, 33, 40 to 42 and 47 to 50 are rejected under 35 U.S.C. §112, second paragraph. Claims 26 to 43, 48 to 50, 52 and 53 are rejected under 35 U.S.C. §112, first paragraph. Claims 26 to 43, 48 to 50, 52 and 53 are rejected under 35 U.S.C. §102.

Applicants respectfully traverse all outstanding rejections of the claims.

#### The Telephonic Interview of February 12, 2004

Applicants thank the Examiner for the very courteous and helpful telephonic interview of February 12, 2004. In the interview, the outstanding rejections and proposed claim amendments addressing these issues were discussed. Applicants have endeavored to address all the outstanding issues set forth in the final office action of July 29, 2003, and as discussed in the telephonic interview, in the instant amendment.

#### Support for the Claim Amendments

Support for the new and amended claims can be found throughout the application for the skilled artisan. For example, support for claims directed to oligonucleotide probes that hybridize under specific conditions can be found, inter alia, page 9, line 24, to page 10, line 6, of the specification. Claims directed to use of oligonucleotide probes of specific lengths can be found, inter alia, on page 12, third paragraph, and page 13, second and third full paragraphs. Claims directed to use of oligonucleotide probes as amplification primers or diagnostic probes can be found, inter alia, on page 13, second full paragraph, and, page 26, first paragraph, and page 28, Example 2. Applicants submit that no new matter is introduced by the instant amendment.

#### Issues under 35 U.S.C. §112, second paragraph

Claims 32, 33, 40 to 42 and 47 to 50 are rejected under 35 U.S.C. §112, second paragraph, for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regards as the invention.

##### *The phrase "comprising a nucleic acid sequence consisting of a sequence..."*

The Patent Office alleges that claim 26 is confusing in the recitation of "comprising a nucleic acid sequence consisting of a sequence..." because of the combination of the open language of the term "comprising" with the closed language of the term "consisting of." The instant amendment addresses this issue.

##### *The term "stringent conditions"*

The Patent Office alleges that claim 26 is indefinite in the recitation of "stringent conditions." The instant amendment addresses this issue.

*The phrase "specifically hybridizes to a nucleic acid ..."*

The Patent Office alleges that claim 27 is indefinite in the recitation of "specifically hybridizes to a nucleic acid having at least 95% identify to SEQ ID NO:23." The instant amendment addresses this issue.

In light of the foregoing amendments and remarks, Applicants respectfully request reconsideration and withdrawal of the rejection of claims based upon 35 U.S.C. §112, second paragraph.

Issues under 35 U.S.C. §112, first paragraph

Claims 26 to 43, 48 to 50, 52 and 53 are rejected under 35 U.S.C. §112, first paragraph.

Written Description

The Patent Office alleges that the specification does not contain any disclosure of the structure and function of the genus of oligonucleotide probes which comprise a sequence which specifically hybridizes to SEQ ID NO:23, its complement or to a nucleic acid having 95% identity thereto. It is alleged that claims directed to a genus of probes are not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s) at the time the application was filed, had possession of the claimed invention.

To address the Examiner's concerns, as discussed in the telephonic interview, Applicants have amended the appropriate claims to add the limitation that nucleic acids having at least 95% identity to SEQ ID NO:23 encode a polypeptide having esterase activity. Claims incorporating hybridization conditions limitations have been amended to add the limitation of a wash step, thus effectively increasing the stringency of the hybridization conditions.

In light of these amendments, Applicants respectfully submit that the claimed invention is sufficiently described in the specification so that one of ordinary skill in the art would be able to ascertain the scope of the claims with reasonable clarity and recognize that Applicants' were in possession of the claimed invention at the time of filing. Applicants respectfully aver that describing a genus of polynucleotides in terms of its physico-chemical properties (e.g., stringent hybridization conditions, including a wash step) and function (e.g.,

nucleic acids having at least 95% identity to SEQ ID NO:23 encode a polypeptide having esterase activity) satisfies the written description requirement of section 112, first paragraph.

Accordingly, Applicants respectfully submit that the pending claims meet the written description requirement under 35 U.S.C. §112, first paragraph.

#### Enablement

The Patent Office notes that the specification enables a probe consisting of a fragment of SEQ ID NO:23 which will hybridize to SEQ ID NO:23 under stringent conditions and optionally a detectable label. However, it is alleged that the specification does not reasonably provide enablement for a genus of oligonucleotide probes which specifically hybridizes to any nucleic acid having 95% identity to SEQ ID NO:23 under any conditions. It is alleged, inter alia, that designing probes which would specifically detect any particular sequence under any conditions would require undue experimentation.

As discussed above, Applicants believe that entry of the instant amendments addresses the Examiner's concerns. To address the Examiner's concerns, as discussed in the telephonic interview, Applicants have amended the appropriate claims to add the limitation that nucleic acids having at least 95% identity to SEQ ID NO:23 encode a polypeptide having esterase activity. Claims incorporating hybridization conditions limitations have been amended to add the limitation of a wash step, thus effectively increasing the stringency of the hybridization conditions.

Accordingly, Applicants respectfully submit that the pending claims meet the enablement requirement under 35 U.S.C. §112, first paragraph.

#### Issues under 35 U.S.C. §102

Claims 26 to 43, 48 to 50, 52 and 53 are rejected under 35 U.S.C. §102 (a or b), as allegedly anticipated by Kim, et al., or GenBank Accession No. X86487. To address the Examiner's concerns, as discussed in the telephonic interview, Applicants have amended the appropriate claims to add a length limitation to address this issue.

CONCLUSION

In view of the foregoing amendment and remarks, Applicants respectfully aver that the Examiner can properly withdraw the rejection of the pending claims under 35 U.S.C. §112, first and second paragraphs, and 35 U.S.C. §102. Applicants respectfully submit that all claims pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

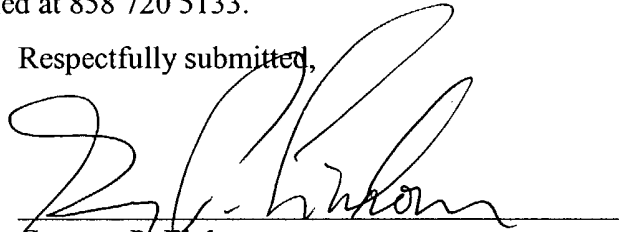
Applicants believe that no additional fees are necessitated by the present response and amendment. However, in the event any such fees are due, the Commissioner is hereby authorized to charge any such fees to Deposit Account No. 03-1952. Please credit any overpayment to this account.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 858 720 5133.

Respectfully submitted,

Date:

Feb. 19, 2004

  
\_\_\_\_\_  
Gregory P. Einhorn  
Reg. No. 38,440

Morrison & Foerster LLP  
3811 Valley Centre Drive, Suite 500  
San Diego CA 92130  
direct dial 858 720 5133  
fax 858 720 5125